Remarks

Claims 1, 7, 8, 10-19, 21, 23, 33-38, 40, 41, 43, 45, 50-54, 61, 62, 71, 73, 74, 83, 85, 88, 92-102, 106-124, 130-155 are presently pending in the subject application.

Reconsideration and allowance are respectfully requested in view of the above amendments and the following remarks.

Claims 2-6, 9, 30-32, 39, 72, 103-105 and 125-129 are canceled herein without prejudice to the prosecution of the subject matter of this claims in this or a future continuing application.

The claims have been amended herein to, *inter alia*, introduce length limitations to the target binding portions of the recited hybridization assay probes, amplification oligonucleotides and helper oligonucleotides. *See, e.g.,* specification at page 4, lines 22-26; page 5, lines 10-12; and page 31, lines 7-9. The claims have further been amended herein to specify the claimed probes and amplification oligonucleotides do not include base regions in addition to the recited target binding regions that are capable of stably binding to the target nucleic acid under the indicated conditions of use. *See, e.g.,* specification at page 20, lines 22-25; and page 44, lines 7-11. The claims have also been amended herein to replace the phrase "amplification primer" with the phrase "amplification oligonucleotide" to clarify that the claimed amplification oligonucleotides do not have function as primers. *See, e.g.,* specification at page 20, lines 19-22. Additionally, to clarify that the claimed probes will bind to and form a hybrid stable for detection with nucleic acid from more than one species of *Cryptosporidium*, the claims have been amended herein to replace the phrase "a *Cryptosporidium* organism" with "*Cryptosporidium* organisms." *See, e.g.,* specification at page 43, lines 3-8. Finally, many of the claims have been amended herein to simplify and/or clarify the claim language consistent with Applicants' disclosure. A clean copy of the amended claims is attached hereto for the Examiner's convenience. *See* Attachment A.

Non-Elected Subject Matter

Claim 21 has been withdrawn by the Examiner as being drawn to non-elected subject matter. Applicants respectfully request reconsideration by the Examiner. Claim 21 depends from claim 19 and recites a second helper oligonucleotide which hybridizes to a target sequence present in nucleic acid derived from *Cryptosporidium* organisms. Applicants disclose this claimed pair of helper oligonucleotides as a preferred combination for use with the hybridization assay probe of claim 1. *See* specification at page 52, lines 8-15. Thus, if the Examiner does not permit Applicants to maintain the subject matter of claim 21 in the present application, then it would appear that there is no circumstance in which Applicants would be permitted to claim this preferred probe mix. *See* paragraph 3 of the Examiner's Restriction Requirement mailed on November 22, 2002.

Objection to the Specification

The disclosure is objected to by the Examiner for containing an embedded hyperlink. Applicants provided this hyperlink to ensure that their disclosure fully enabled the claimed invention and did not intend for this hyperlink to be an active link. Accordingly, withdrawal of this objection is respectfully requested with the understanding that the Office will disable this hyperlink when preparing the text to be loaded onto the USPTO web database. *See* MPEP § 608.01.

Rejection Under 35 U.S.C. § 112

Claims 1-19, 21, 23, 30-41, 43, 45, 50-54, 61, 62, 71-74, 83, 85, 88 and 92-155 stand rejected by the Examiner under 35 U.S.C. § 112, first paragraph, as lacking written description support. Applicants submit that this rejection is rendered moot by the amendments to the claims herein. Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 1-3, 7, 15 and 16-19 stand rejected by the Examiner under 35 U.S.C. § 102(a) as being anticipated by Nelson (GenBank Accession No. AA167899, August 23, 2000). The

Examiner contends that Nelson discloses a nucleic acid from the *Cryptosporidium parvum* 18S ribosomal RNA gene which contains the sequences of sequence identifiers 1, 21, 22, 45, 46 and 48. While the Examiner has not addressed all of the limitations of the rejected claims, Applicants nevertheless submit that basis for this rejection is rendered moot by the amendments to the claims herein. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 1-3, 7, 15 and 16-19 stand rejected by the Examiner under 35 U.S.C. § 102(e) as being anticipated by Wick *et al.* (U.S. Patent No. 6,063,604, May 16, 2000). In support of this rejection, the Examiner contends that Wick discloses a nucleic acid from the *Cryptosporidium parvum* 18S ribosomal RNA gene which contains the sequences of sequence identifiers 1, 21, 22, 45, 46 and 48. While the Examiner has not addressed all of the limitations of the rejected claims, Applicants nevertheless submit that the basis for this rejection is rendered moot by the amendments to the claims herein. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 1-3, 16-19, 23, 30, 31, 38-41, 43, 45 and 92-108 stand rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by Brennan (U.S. Patent No. 5,474,796, December 12, 1995). In support of this rejection, the Examiner contends that Brennan discloses oligonucleotides having 10 nucleotides each and that the oligoonucleotides of Brennan represent every possible permutation of the instant claims. Applicants first note that the Examiner has not identified where Brennan provides support for this conclusion. Moreover, the Examiner has not established how Brennan enables the specifically claimed hybridization assay probes, amplification oligonucleotides and amplification oligonucleotide sets, and probe mixes. Notwithstanding, Applicants submit that the basis for this rejection is rendered moot by the amendments to the claims herein. Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 1-6, 10, 13-15, 16-19, 23, 30-31, 38-41, 43, 45, 50-54, 61, 62, 71-74, 83, 85 and 92-155 stand rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Zhu *et al.* (*J. Infectious Disease*, Vol. 177, pages 1443-1446, 1998) in view of Fenger *et al.* (U.S. Patent No. 6,110,665, August 29, 2000) and Wick *et al.* (U.S. Patent No. 6,063,604, May 16, 2000) in view of Hogan *et al.* (U.S. Patent No. 5,595,874, January 21, 1997). Applicants respectfully traverse this rejection for the reasons that follow.

The Examiner submits that Zhu teaches a method of detecting *Cryptosporidium* using genus-specific primers from the 18S rRNA. While conceding that Zhu does not teach using SEQ ID NO:1 as the target sequence for the probes and primers, the Examiner urges that Fenger provides an alignment that shows variability in the region of SEQ ID NO:1 and further discloses sequences containing the sequences of sequence identifiers 21 and 22. Without stating how Wick is to be read in combination with the other cited references, the Examiner merely states that Wick provides the entire 18S rRNA gene of *Cryptosporidium parvum*, which contains the sequences of sequence identifiers 1, 21 and 48. Finally, Hogan is cited by the Examiner for teaching a method of comparing rRNA variable region sequences to distinguish between organisms. From these disclosures, the Examiner concludes that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the genus-specific primers of Zhu using the alignment provided by Fenger and the guidance taught by Hogan to obtain the invention as a whole.

Applicants first note that although Zhu teaches a pair of primers specific to the genus *Cryptosporidium*, the probe used by Zhu was specific for *Cryptosporidium parvum*. *See* Zhu at col. 2 on page 1443 and at col. 2 on page 1444. This differs from the present invention, in which the claimed hybridization assay probes hybridize to a target sequence present in nucleic acid derived from *Cryptosporidium* organisms. Applicants' specification provides that a probe for detecting the presence of *Cryptosporidium* organisms is capable of detecting the presence of at least two species

belonging to the *Cryptosporidium* genus under stringent conditions. *See* specification at page 43, lines 3-8. Thus, Applicants submit that Zhu does not provide a motivation for the objective of the presently claimed invention — detection of multiple members of the *Cryptosporidium* genus.

Second, while Fenger provides a sequence comparison of portions of the small ribosomal subunits of a number of organisms, including *Cryptosporidium parvum*, Fenger does not disclose small ribosomal subunit (SRSU) sequences of any other *Cryptosporidium* orgnanisms, as would be required in the selection of a genus-specific probe, nor does Fenger disclose a comparison the *Cryptosporidium parvum* sequence with many organisms expected to be present in a test sample containing *Cryptosporidium* organisms and that a selected probe would have to distinguish over. *See, e.g.,* Zhu at col. 2 on page 1444; *see also* specification at page 45, lines 16-18. Also, Figure 2 of Fenger suggests that *Cryptosporidium parvum* is not closely related to the other organisms whose SRSU sequences are being compared. *See* Fenger at paragraph bridging cols. 4 and 5.

Finally, since the probes of the present invention are genus-specific probes for use in determining the presence of *Cryptospordium* organisms (as opposed to *Cryptosporidium parvum* alone) in a test sample, the claimed probes and primers cannot be viewed as "functional equivalents" of the probes and primers of Zhu. And although Zhu discloses one set of genus-specific primers, (*see* Zhu at col. 2 on page 1444), those primers, unlike claimed invention, amplify a region of 18S ribosomal nucleic acid that is indicated to be specific for the detection of *Cryptosporidium parvum*. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 7-9, 11-14 and 32-37 stand rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Zhu *et al.* (*J. Infectious Disease*, Vol. 177, pages 1443-1446, 1998) in view of Fenger *et al.* (U.S. Patent No. 6,110,665, August 29, 2000) and Wick *et al.* (U.S. Patent No. 6,063,604, May 16, 2000) in view of Hogan *et al.* (U.S. Patent No. 5,595,874, January 21, 1997) as applied to claims 1-6, 10, 13-15, 16-19, 23, 30, 31, 38-41, 43, 45, 50-54, 61, 62, 71-74, 83, 85 and

92-155, and further in view of Becker *et al.* (U.S. Patent No. 6,361,945, March 26, 2002). Applicants submit that the teachings of Becker do not overcome the deficiencies noted above in the teachings of Zhu and Fenger when combined with the teachings of Wick and Hogan. Accordingly, withdrawal of this rejection is respectfully requested.

Applicants submit that the subject application is in condition for allowance and early Notice to that effect is earnestly solicited.

Please charge any fees due in connection with this Reply, including the fee for a three-month extension of time, to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

Certificate of Transmission

I hereby certify that this correspondence (and any referred to as attached) is being sent by facsimile to 703-872-9306 on the date indicated below to the Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Respectfully Submitted,

Date: December 23, 2003 By: _____

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ATTACHMENT A

Clean Copy of Amended Claims

1. (Currently Amended) A hybridization assay probe comprising a target binding region from 18 to 35 bases in length that hybridizes to a target sequence present in target nucleic acid derived from *Cryptosporidium* organisms in a test sample under stringent conditions to form a probe:target hybrid stable for detection, said target sequence being selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, wherein said probe does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in said test sample to form a probe:non-target hybrid stable for detection under said conditions.

Claims 2-6 (Canceled)

7. (Currently Amended) The probe of claim 1, wherein said probe contains at least two base regions that hybridize to each other when said probe is not hybridized to said target sequence under said conditions.

8. (Currently Amended) The probe of claim 1, wherein said probe comprises at least one base region that does not stably hybridize to nucleic acid derived from *Cryptosporidium* organisms under said conditions.

9. Canceled

10. (Original) The probe of claim 1 further comprising a detectable label.

11. (Original) The probe of claim 7 further comprising a group of interacting labels.

12. (Original) The probe of claim 11, wherein said interacting labels include a luminescent label and a quencher label.

13. (Currently Amended) The probe of claim 1, wherein said target binding region includes at least one ribonucleotide modified to include a 2'-O-methyl substitution to the ribofuranosyl moiety.

14. (Currently Amended) The probe of claim 1, wherein a pseudo peptide backbone joins at least a portion of the bases of said target binding region.

15. (Currently Amended) The probe of claim 1, wherein said conditions comprise 50 mM succinic acid, 1% (w/v) LLS, 7.5 mM aldrithiol-2, 0.6 M LiCl, 115 mM LiOH, 10 mM EDTA, 10 mM EGTA, 1.5% (v/v) ethyl alcohol (absolute), pH to 4.7, and a test sample temperature of about 60°C.

16. (Currently Amended) The probe of claim 1, wherein the base sequence of said target binding region is at least 80% complementary to the base sequence of said target sequence.

17. (Currently Amended) The probe of claim 1, wherein the base sequence of said probe is at least 80% complementary to the base sequence of said target sequence.

18. (Currently Amended) The probe of claim 1, wherein the base sequence of said probe is fully complementary to the base sequence of said target sequence.

19. (Currently Amended) A probe mix comprising said probe of claim 1 and a first helper oligonucleotide from 18 to 35 bases in length which hybridizes to a target sequence selected from the group consisting of SEQ ID NO:21, SEQ ID NO:23, SEQ ID NO:25 and SEQ ID NO:27 under said conditions.

20. Canceled

21. (Withdrawn) The probe mix of claim 19 further comprising a second helper oligonucleotide having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence, wherein the target sequence of said second helper oligonucleotide is selected from the group consisting of SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26 and SEQ ID NO:28.

22. Canceled

23. (Currently Amended) An amplification oligonucleotide for use in amplifying a nucleic acid sequence present in target nucleic acid derived from *Cryptosporidium* organisms, said amplification oligonucleotide comprising a target binding region from 18 to 40 bases in length which hybridizes to a target sequence selected from the group consisting of SEQ ID NO:48, SEQ ID NO:54, SEQ ID NO:60 and SEQ ID NO:66 under amplification conditions, wherein said amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and wherein said amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

Claims 24-32 (Canceled)

33. (Currently Amended) The amplification oligonucleotide of claim 23, wherein said amplification oligonucleotide includes said 5' sequence.

34. (Currently Amended) The amplification oligonucleotide of claim 33, wherein said 5' sequence is a T7 promoter having the base sequence of SEQ ID NO:69.

35. (Currently Amended) The amplification oligonucleotide of claim 23, wherein said amplification oligonucleotide contains at least two base regions that hybridize to each other when said amplification oligonucleotide is not hybridized to said target sequence under said conditions.

36. (Currently Amended) The amplification oligonucleotide of claim 35 further comprising a group of interacting labels.

37. (Currently Amended) The amplification oligonucleotide of claim 36, wherein said interacting labels include a luminescent label and a quencher label.

38. (Currently Amended) The amplification oligonucleotide of claim 23, wherein the base sequence of said target binding region is at least 80% complementary to the base sequence of said target sequence.

39. Canceled

40. (Currently Amended) The amplification oligonucleotide of claim 23, wherein the base sequence of said target binding region is fully complementary to the base sequence of said target sequence.

41. (Currently Amended) A set of amplification oligonucleotides for use in amplifying a nucleic acid sequence present in target nucleic acid derived from *Cryptosporidium* organisms, said set of amplification oligonucleotides including first and second amplification oligonucleotides, wherein:

said first amplification oligonucleotide is said amplification oligonucleotide of claim 23; and

said second amplification oligonucleotide comprises a target binding region from 18 to 40 bases in length which hybridizes to a target sequence selected from the group consisting of

SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:57, SEQ ID NO:58, SEQ ID NO:63 and SEQ ID NO:64 under amplification conditions, wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

42. Canceled

43. (Currently Amended) The set of amplification oligonucleotides of claim 41, wherein said target sequence of said second amplification oligonucleotide is selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63.

44. Canceled

45. (Currently Amended) The set of amplification oligonucleotides of claim 41, wherein said target sequence of said second amplification oligonucleotide is selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64.

Claims 46-49 (Canceled)

50. (Currently Amended) A method for determining the presence of *Cryptosporidium* organisms in a test sample, said method comprising the steps of:

contacting said test sample with said probe of claim 1 under stringent conditions; and

determining whether a probe:target hybrid has formed as an indication of the presence of *Cryptosporidium* organisms in said test sample.

51. (Currently Amended) A method for determining the presence of *Cryptosporidium* organisms in a test sample, said method comprising the steps of:

contacting said test sample with said probe of claim 16 under stringent conditions; and

determining whether a probe:target hybrid has formed as an indication of the presence of *Cryptosporidium* organisms in said test sample.

52. (Currently Amended) A method for determining the presence of *Cryptosporidium* organisms in a test sample, said method comprising the steps of:

contacting said test sample with said probe of claim 17 under stringent conditions; and

determining whether a probe:target hybrid has formed as an indication of the presence of *Cryptosporidium* organisms in said test sample.

53. (Currently Amended) A method for determining the presence of *Cryptosporidium* organisms in a test sample, said method comprising the steps of:

contacting said test sample with said probe of claim 18 under stringent conditions; and

determining whether a probe:target hybrid has formed as an indication of the presence of *Cryptosporidium* organisms in said test sample.

54. (Currently Amended) A method for amplifying *Cryptosporidium* nucleic acid that may be present in a test sample, said method comprising the steps of:

contacting said test sample with said amplification oligonucleotide of claim 23 under amplification conditions; and

amplifying a target sequence present in target nucleic acid derived from *Cryptosporidium* organisms that may be present in said test sample.

Claims 55-60 (Canceled)

61. (Currently Amended) The method of claim 54 further comprising the step of providing to said test sample a hybridization assay probe for use in determining whether said target sequence was amplified in said amplifying step.

62. (Currently Amended) The method of claim 61, wherein said probe comprises a target binding region from 18 to 35 bases in length that hybridizes to said target sequence or the complement thereof under stringent conditions to form a probe:target hybrid stable for detection, said target sequence or the complement thereof being selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, wherein said probe does not comprise a base region in addition to said target binding region that is capable of stably binding to nucleic acid derived from *Cryptosporidium* organisms under said conditions, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in said test sample to form a probe:non-target hybrid stable for detection under said conditions.

Claims 63-70 (Canceled)

71. (Currently Amended) A method for amplifying *Cryptosporidium* nucleic acid that may be present in a test sample, said method comprising the steps of:

contacting said test sample with said amplification oligonucleotide of claim 38 under amplification conditions; and

amplifying a target sequence present in target nucleic acid derived from *Cryptosporidium* organisms that may be present in said test sample.

72. Canceled

73. (Currently Amended) A method for amplifying *Cryptosporidium* nucleic acid that may be present in a test sample, said method comprising the steps of:

contacting said test sample with said amplification oligonucleotide of claim 40 under amplification conditions; and

amplifying a target sequence present in target nucleic acid derived from *Cryptosporidium* organisms that may be present in said test sample.

74. (Currently Amended) A kit comprising, in packaged combination, first and second oligonucleotides for use in determining the presence of *Cryptosporidium* organisms in a test sample, each of said oligonucleotides comprising a target binding region which hybridizes to a target sequence present in target nucleic acid derived from *Cryptosporidium* organisms under hybridization conditions, said target binding region of said first oligonucleotide being from 18 to 35 bases in length and said target binding region of said second oligonucleotide being from 18 to 40 bases in length,

wherein said target sequence of said first oligonucleotide is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4,

wherein said target sequence of said second oligonucleotide is selected from the group consisting of SEQ ID NO:48, SEQ ID NO:54, SEQ ID NO:60 and SEQ ID NO:66,

wherein neither of said first and second oligonucleotides comprises a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and

wherein said second oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

Claims 75-82 (Canceled)

83. (Currently Amended) The kit of claim 74 further comprising a third oligonucleotide, said third oligonucleotide comprising a target binding region from 18 to 40 bases in length which hybridizes to a target sequence present in target nucleic acid derived from *Cryptosporidium* organisms under hybridization conditions, said target sequence being selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63, wherein said third oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and wherein

said third oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

84. Canceled

85. (Currently Amended) The kit of claim 74 further comprising a third oligonucleotide, said third oligonucleotide comprising a target binding region from 18 to 40 bases in length which hybridizes to a target sequence present in target nucleic acid derived from *Cryptosporidium* organisms under hybridization conditions, said target sequence being selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64, wherein said third oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and wherein said third oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

Claims 86 and 87 (Canceled)

88. (Currently Amended) A kit comprising, in packaged combination, first and second oligonucleotides for use in determining the presence of *Cryptosporidium* organisms in a test sample, each of said oligonucleotides comprising a target binding region from 18 to 35 bases in length that hybridizes to a target sequence present in target nucleic acid derived from *Cryptosporidium* organisms under stringent conditions,

wherein said target sequence of said first oligonucleotide is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4,

wherein said target sequence of said second oligonucleotide is selected from the group consisting of SEQ ID NO:21, SEQ ID NO:23, SEQ ID NO:25 and SEQ ID NO:27,

wherein neither of said first and second oligonucleotides comprises a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and

wherein said first oligonucleotide does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in said test sample to form a probe:non-target hybrid stable for detection under said conditions.

Claims 89-91 (Canceled)

92. (Currently Amended) The probe of claim 1, wherein the base sequence of said target binding region is fully complementary to the base sequence of said target sequence.

93. (Currently Amended) A probe mix comprising said probe of claim 16 and a first helper oligonucleotide, wherein the base sequence of said first helper oligonucleotide is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:21, SEQ ID NO:23, SEQ ID NO:25 and SEQ ID NO:27.

94. (Previously Added) The probe mix of claim 93 further comprising a second helper oligonucleotide, wherein the base sequence of said second helper oligonucleotide is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26 and SEQ ID NO:28.

95. (Currently Amended) A probe mix comprising said probe of claim 17 and a first helper oligonucleotide, wherein the base sequence of said first helper oligonucleotide is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:21, SEQ ID NO:23, SEQ ID NO:25 and SEQ ID NO:27.

96. (Previously Added) The probe mix of claim 95 further comprising a second helper oligonucleotide, wherein the base sequence of said second helper oligonucleotide is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26 and SEQ ID NO:28.

97. (Currently Amended) A probe mix comprising said probe of claim 18 and a first helper oligonucleotide, wherein the base sequence of said first helper oligonucleotide is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:21, SEQ ID NO:23, SEQ ID NO:25 and SEQ ID NO:27.

98. (Previously Added) The probe mix of claim 97 further comprising a second helper oligonucleotide, wherein the base sequence of said second helper oligonucleotide is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26 and SEQ ID NO:28.

99. (Currently Amended) The amplification oligonucleotide of claim 38, wherein the base sequence of said target binding region is fully complementary to the base sequence of said target sequence.

100. (Currently Amended) A set of amplification oligonucleotides for use in amplifying a nucleic acid sequence present in target nucleic acid derived from *Cryptosporidium* organisms, said set of amplification oligonucleotides including first and second amplification oligonucleotides, wherein:

said first amplification oligonucleotide is said amplification oligonucleotide of claim 38; and

said second amplification oligonucleotide comprises a target binding region, wherein the base sequence of said target binding region is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:57, SEQ ID NO:58, SEQ ID NO:63 and SEQ ID NO:64,

wherein said target binding region of said second amplification oligonucleotide hybridizes to said target sequence under amplification conditions,

wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and

wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

101. (Currently Amended) The set of amplification oligonucleotides of claim 100, wherein said target sequence of said second amplification oligonucleotide is selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63.

102. (Currently Amended) The set of amplification oligonucleotides of claim 100, wherein said target sequence of said second amplification oligonucleotide is selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64.

Claims 103-105 (Canceled)

106. (Currently Amended) A set of amplification oligonucleotides for use in amplifying a nucleic acid sequence present in target nucleic acid derived from *Cryptosporidium* organisms, said set of amplification oligonucleotides including first and second amplification oligonucleotides, wherein:

said first amplification oligonucleotide is said amplification oligonucleotide of claim 40; and

said second amplification oligonucleotide comprises a target binding region, wherein the base sequence of said target binding region is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:57, SEQ ID NO:58, SEQ ID NO:63 and SEQ ID NO:64,

wherein said target binding region of said second amplification oligonucleotide hybridizes to said target sequence under amplification conditions,

wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and

wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

107. (Currently Amended) The set of amplification oligonucleotides of claim 106, wherein said target sequence of said second amplification oligonucleotide is selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63.

108. (Currently Amended) The set of amplification oligonucleotides of claim 106, wherein said target sequence of said second amplification oligonucleotide is selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64.

109. (Currently Amended) The method of claim 51, wherein the base sequence of said target binding region is fully complementary to the base sequence of said target sequence.

110. (Currently Amended) The method of claim 54 further comprising a second amplification oligonucleotide, said second amplification oligonucleotide comprising a target binding region from 18 to 40 bases in length that hybridizes to a target sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63 under said conditions, wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

111. (Currently Amended) The method of claim 110 further comprising the step of determining the presence of amplicon in said test sample with a hybridization assay probe, wherein said probe comprises a target binding region from 18 to 35 bases in length that hybridizes to a target sequence present in said amplicon under stringent conditions to form a probe:target hybrid

stable for detection, said target sequence being selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, wherein said probe does not comprise a base region in addition to said target binding region that is capable of stably binding to said amplicon under said conditions, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in said test sample to form a probe:non-target hybrid stable for detection under said conditions.

112. (Currently Amended) The method of claim 54 further comprising a second amplification oligonucleotide, said second amplification oligonucleotide comprising a target binding region from 18 to 40 bases in length that hybridizes to a target sequence selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64 under said conditions, wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

113. (Currently Amended) The method of claim 112 further comprising the step of determining the presence of amplicon in said test sample with a hybridization assay probe, wherein said probe comprises a target binding region from 18 to 35 bases in length that hybridizes to a target sequence present in said amplicon under stringent conditions to form a probe:target hybrid stable for detection, said target sequence being selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, wherein said probe does not comprise a base region in addition to said target binding region that is capable of stably binding to said amplicon under said conditions, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in said test sample to form a probe:non-target hybrid stable for detection under conditions.

114. (Currently Amended) The method of claim 71 further comprising the step of determining the presence of amplicon in said test sample with a hybridization assay probe, wherein said probe comprises a target binding region that hybridizes to a target sequence present in said amplicon under stringent conditions to form a probe:target hybrid stable for detection, wherein the base sequence of said target binding region is at least 80% complementary to the base sequence of said target sequence, said target sequence being selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, wherein said probe does not comprise a base region in addition to said target binding region that is capable of stably binding to said amplicon under said conditions, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in said test sample to form a probe:non-target hybrid stable for detection under said conditions.

115. (Currently Amended) The method of claim 71 further comprising a second amplification oligonucleotide comprising a target binding region, wherein the base sequence of said target binding region is at least 80% complementary to the base sequence of a target sequence present in target nucleic acid derived from *Cryptosporidium* organisms, said target sequence being selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63,

wherein said target binding region hybridizes to said target sequence under said conditions,

wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and

wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

116. (Currently Amended) The method of claim 115 further comprising the step of determining the presence of amplicon in said test sample with a hybridization assay probe,

wherein said probe comprises a target binding region that hybridizes to a target sequence present in said amplicon under stringent conditions to form a probe:target hybrid stable for detection, wherein the base sequence of said target binding region is at least 80% complementary to the base sequence of said target sequence, said target sequence being selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, wherein said probe does not comprise a base region in addition to said target binding region that is capable of stably binding to said amplicon under said conditions, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in said test sample to form a probe:non-target hybrid stable for detection under said conditions.

117. (Currently Amended) The method of claim 71 further comprising a second amplification oligonucleotide comprising a target binding region, wherein the base sequence of said target binding region is at least 80% complementary to the base sequence of a target sequence present in target nucleic acid derived from *Cryptosporidium* organisms, said target sequence being selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64,

wherein said target binding region hybridizes to said target sequence under amplification conditions,

wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and

wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

118. (Currently Amended) The method of claim 117 further comprising the step of determining the presence of amplicon in said test sample with a hybridization assay probe, wherein said probe comprises a target binding region that hybridizes to a target sequence present in said amplicon under stringent conditions to form a probe:target hybrid stable for detection, wherein

the base sequence of said target binding region is at least 80% complementary to the base sequence of said target sequence, said target sequence being selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, wherein said probe does not comprise a base region in addition to said target binding region that is capable of stably binding to said amplicon under said conditions, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in said test sample to form a probe:non-target hybrid stable for detection under said conditions.

119. (Currently Amended) The method of claim 71, wherein the base sequence of said target binding region is fully complementary to the base sequence of said target sequence.

120. (Currently Amended) The method of claim 119 further comprising the step of determining the presence of amplicon in said test sample with a hybridization assay probe, wherein said probe comprises a target binding region that hybridizes to a target sequence present in said amplicon under stringent conditions to form a probe:target hybrid stable for detection, wherein the base sequence of said target binding region is fully complementary to the base sequence of said target sequence, said target sequence being selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, wherein said probe does not comprise a base region in addition to said target binding region that is capable of stably binding to said amplicon under said conditions, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in said test sample to form a probe:non-target hybrid stable for detection under said conditions.

121. (Currently Amended) The method of claim 119 further comprising a second amplification oligonucleotide comprising a target binding region, wherein the base sequence of said target binding region is fully complementary to the base sequence of a target sequence present in target nucleic acid derived from *Cryptosporidium* organisms, said target sequence being selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63,

wherein said target binding region of said second amplification oligonucleotide hybridizes to said target sequence under said conditions,

wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and

wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

122. (Currently Amended) The method of claim 121 further comprising the step of determining the presence of amplicon in a test sample with a hybridization assay probe, wherein said probe comprises a target binding region that hybridizes to a target sequence present in said amplicon under stringent conditions to form a probe:target hybrid stable for detection, wherein the base sequence of said target binding region is fully complementary to the base sequence of said target sequence, said target sequence being selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, wherein said probe does not comprise a base region in addition to said target binding region that is capable of stably binding to said amplicon under said conditions, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in said test sample to form a probe:non-target hybrid stable for detection under said conditions.

123. (Currently Amended) The method of claim 119 further comprising a second amplification oligonucleotide comprising a target binding region, wherein the base sequence of said target binding region is fully complementary to the base sequence of a target sequence present in target nucleic acid derived from *Cryptosporidium* organisms, said target sequence being selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64,

wherein said target binding region hybridizes to said target sequence under said conditions,

wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and

wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

124. (Currently Amended) The method of claim 123 further comprising the step of determining the presence of amplicon in said test sample with a hybridization assay probe, wherein said probe comprises a target binding region that hybridizes to a target sequence present in said amplicon under stringent conditions to form a probe:target hybrid stable for detection, wherein the base sequence of said target binding region is fully complementary to the base sequence of said target sequence, said target sequence being selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, wherein said probe does not comprise a base region in addition to said target binding region that is capable of stably binding to said amplicon under said conditions, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in said test sample to form a probe:non-target hybrid stable for detection under said conditions.

Claims 125-129 (Canceled)

130. (Currently Amended) The method of claim 73 further comprising the step of determining the presence of amplicon in said test sample with an oligonucleotide probe, wherein the base sequence of said probe is fully complementary to the base sequence of a target sequence present in said amplicon, said target sequence being selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4.

131. (Currently Amended) The method of claim 73 further comprising a second amplification oligonucleotide comprising a target binding region, wherein the base sequence of said

target binding region is fully complementary to the base sequence of a target sequence present in target nucleic acid derived from *Cryptosporidium* organisms, said target sequence being selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63,

wherein said target binding region hybridizes to said target sequence under said conditions,

wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and

wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

132. (Currently Amended) The method of claim 131 further comprising the step of determining the presence of amplicon in said test sample with an oligonucleotide probe, wherein the base sequence of said probe is fully complementary to the base sequence of a target sequence present in said amplicon, said target sequence being selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4.

133. (Currently Amended) The method of claim 73 further comprising a second amplification oligonucleotide comprising a target binding region, wherein the base sequence of said target binding region is fully complementary to the base sequence of a target sequence present in target nucleic acid derived from *Cryptosporidium* organisms, said target sequence being selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64,

wherein said target binding region hybridizes to said target sequence under said conditions,

wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and

wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

134. (Currently Amended) The method of claim 133 further comprising the step of determining the presence of amplicon in said test sample with an oligonucleotide probe, wherein the base sequence of said probe is fully complementary to the base sequence of a target sequence present in said amplicon, said target sequence being selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4.

135. (Currently Amended) The kit of claim 74, wherein the base sequence of said target binding region of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

136. (Currently Amended) The kit of claim 74, wherein the base sequence of said target binding region of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

137. (Currently Amended) The kit of claim 74, wherein the base sequence of each of said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

138. (Currently Amended) The kit of claim 74, wherein the base sequence of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

139. (Currently Amended) The kit of claim 83, wherein the base sequence of said target binding region of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

140. (Currently Amended) The kit of claim 83, wherein the base sequence of said target binding region of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

141. (Currently Amended) The kit of claim 83, wherein the base sequence of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

142. (Currently Amended) The kit of claim 83, wherein the base sequence of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

143. (Currently Amended) The kit of claim 85, wherein the base sequence of said target binding region of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence.

144. (Currently Amended) The kit of claim 85, wherein the base sequence of said target binding region of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

145. (Currently Amended) The kit of claim 85, wherein the base sequence of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

146. (Currently Amended) The kit of claim 85, wherein the base sequence of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

147. (Currently Amended) The kit of claim 88, wherein the base sequence of said target binding region of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

148. (Currently Amended) The kit of claim 88, wherein the base sequence of said target binding region of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

149. (Currently Amended) The kit of claim 88, wherein the base sequence of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

150. (Currently Amended) The kit of claim 88, wherein the base sequence of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

151. (Currently Amended) The kit of claim 88 further comprising a third oligonucleotide from 18 to 35 bases in length that hybridizes to a target sequence present in target nucleic acid derived from *Cryptosporidium* organisms under said conditions, said target sequence being is selected from the group consisting of SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26 and SEQ ID NO:28.

152. (Currently Amended) The kit of claim 151, wherein the base sequence of said target binding region of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

153. (Currently Amended) The kit of claim 151, wherein the base sequence of said target binding region of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

154. (Currently Amended) The kit of claim 151, wherein the base sequence of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

155. (Currently Amended) The kit of claim 151, wherein the base sequence of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.